

REMARKS/ARGUMENTS

Amendments to the Claims

Claims 1–2, 5–11, 13–14, 16–21, 23–34, and 48–54 are pending. Claims 3–4, 12, 15, 22, and 35–47 are canceled without prejudice or disclaimer. Claims 1–2, 5–11, 13–14, 16–21, 23–33, and 48–53 were previously presented. Claims 34 and 54 are currently amended. Support for the amended claims can be found in the original claims and the specification. No new matter has been added.

Applicants respectfully request that all amendments to the claims, specification and figure be entered and considered by the Examiner.

Amendments to the Specification

Applicants have amended paragraphs [0013], [0030], [0031], [0066], [0145], and [0165] through [0171] of the Specification. The specification further has been amended to insert a paragraph incorporating by reference the replacement Sequence Listing filed herewith *via* EFS Web, as detailed below.

The Examiner has objected under MPEP § 608.01 to the presence of embedded hyperlinks in the Specification. Applicants have amended paragraphs [0013], [0030], [0031], [0066], and [0145] of the Specification to delete embedded hyperlinks and to correct other minor informalities detected in those otherwise amended paragraphs. Applicants also have inserted language to clarify the citations left lacking by deletion of the hyperlinks. All such language is disclosed elsewhere in the Specification or is ministerial in nature. No new matter has been added.

Applicants note that the paragraph numbers of the amended paragraphs differ slightly from the paragraph numbers cited by the Examiner on page 9 of the Office action. Applicants cannot explain this discrepancy but believe those paragraphs cited by the Examiner and amended by Applicants are the same. Applicants' representative would be happy to interview the Examiner to resolve this discrepancy at any time the Examiner might wish.

Applicants have amended paragraphs [0165] through [0171] of the Specification, which are the paragraphs entitled "Description of the Figures", to insert SEQ ID NOs: corresponding to

the SEQ ID NOs: in the replacement Sequence Listing filed herewith. Applicants also have replaced text in bold and italic fonts with identical text in standard fonts within these paragraphs. No new matter has been added.

Replacement Sequence Listing

The Examiner pointed out that SEQ ID NOs: were not related to the sequences presented in Figures 1 and 2. Applicants herewith file a replacement Sequence Listing, which adds sequences 2-4 in each of Figures 1 and 2. Applicants submit herewith a replacement Computer Readable Form of the Sequence Listing as a text file *via* EFS Web, and a Statement to Support Filing and Submission in Accordance with 37 CFR §§ 1.821-1.825. No new matter has been added to the replacement Sequence Listing unsupported by the Sequence Listing as-filed and the Specification as filed. Please delete the Sequence Listing filed with the published International application and enter this replacement Sequence Listing into the application.

Specifically, and as shown in amended paragraphs [0165] and [0166] herein, Figure 1 discloses amino acid sequence 1 (SEQ ID NO:2), sequence 2 (SEQ ID NO: 34), sequence 3 (SEQ ID NO:36), and sequence 4 (SEQ ID NO: 38), while Figure 2 discloses nucleic acid sequence 1 (SEQ ID NO:1), sequence 2 (SEQ ID NO: 33), sequence 3 (SEQ ID NO:35), and sequence 4 (SEQ ID NO: 37). Support for these sequences newly added to the sequence listing is found in Figure 1, as amended herein, and Figure 2. No new matter has been added.

Applicants specifically request and direct that the replacement Sequence Listing filed herewith be entered into this application.

Amendments to the Figures

Applicants have amended Figure 1 to correct obvious errors in the sequence 1, described in the "Description of Figures" as "Factor RecA from *B. licheniformis* DSM 13 (SEQ ID NO: 2). Sequence 1 of Figure 1 contains typographical errors by which the amino acids at positions 31, 33, 37, 71, 72, 95, 119, 185, 206, 207, 240, 255, 277, and 329 are labeled "U". The "U" in each of these positions was changed to "T". Support for these amendments is found in SEQ ID NOs: 1 and 2 and the nucleic acid sequence of the corresponding nucleic acid sequence 1 in Figure 2.

The disclosures of SEQ ID NOs: 1 and 2 and Figure 2 indicate that the “U”, for which Applicants are unaware of such a one-letter amino acid designation, should have been entered as “T”. No new matter has been added.

Additionally, Applicants noticed an “S” at position 350 of sequence 1 of Figure 1 erroneously added after the terminal “F” at position 348 and “.” (“taa” stop codon at position 1047 in Figure 2 and SEQ ID NO: 1). While the codon in Figure 2, sequence 1, positions 147–150 encodes a serine, the person of ordinary skill in the art would understand that this codon immediately following a stop codon would be unlikely to be translated. Support for this amendment is found in the Specification at paragraph [0030] (“All positions from 1 to 1047 encode for the protein; the last three represent the stop codon.”), and in SEQ ID NOs: 1 and 2, and in the nucleic acid sequence of the corresponding sequence 1 in Figure 2, sequence 1. No new matter has been added.

Interview Summary

Applicants thank the Examiner for responding to the May 1, 2009 telephonic inquiry of Applicants’ representative seeking the Examiner’s clarification of the claims encompassed by Group IV of the restricted claim groups in the pending Office action. Applicants’ representative understands the Examiner to have explained in her Interview Summary (PTOL-413) that Group IV consists of claims 17–21 and 23–28. If the representative’s understanding is correct, the Examiner and Applicants’ representative agree that the Examiner’s Interview Summary is an accurate representation.

Claim Objections

The Examiner has objected to the form of claims 34 and 54 as being in improper, simultaneous multiply dependent form. Applicants have amended claims 34 and 54, which are included in the Amendments to the Claims section of this paper, to remove the simultaneous multiple dependencies. Applicants believe that these claims now comply with 37 CFR 1.75(c) and MPEP § 608.01(n), and respectfully request that, in view of these amendments, the Examiner withdraw her objections.

Lack of Unity of Invention

The restriction requirement contained in the Office action dated April 17, 2009 respectfully is traversed. Applicants respectfully assert that unity of invention is established among all pending claims 1, 2, 5–11, 13, 14, 16–21, 23–33, and 48–53, which the Examiner has restricted to nine groups consisting of Groups I– IX.

The Examiner has set forth lack of unity of invention in light of SEQ ID NOs: 1 and 1819 disclosed in US Pat. Pub. 2008/005077 to Berka et al. The Examiner has asserted that unity of invention does not exist between Groups I– IX because these groups are not so linked as to form a single general inventive concept under PCT Rule 13.1, and share a special technical feature under PCT Rule 13.2, which is RecA from *Racillus licheniformis* DSM 13. The Examiner asserts that the claimed RecA does not qualify as a single general inventive concept because it does not make a contribution over the prior art as taught by Berka et al.

Applicants respectfully disagree with the Examiner's contention that Applicants' claimed invention does not make a contribution over the teachings of Berka et al. in US Pat. Pub. 2008/005077 ("077 publication"), which claims benefit of the filing date, *inter alia*, of US Provisional Appl. No. 60/535,988 ("988 provisional"). Berka et al. isolated and sequenced the entire chromosome of *B. licheniformis* ATCC 14580. Berka et al. at [0012]. They identified genes by searching this genomic sequence for ORFs. *Id.* at [0250]. They then compared the theoretical amino acid sequences of these ORFs with the amino acid sequences of identified proteins in other organisms to hypothesize the functional identity of the protein that might be translated from an RNA transcript of the putative gene. *Id.* at [0254] *et seq.* One such example,

as the Examiner noted, is SEQ ID NO: 1819, which Berka et al. putatively identified, based on homology with a *B. amyloliquefasciens* sequence, as RecA protein. *See id.* at Table 1, page 67.

Notably, however, Berka et al. identified SEQ ID NO: 1819 in the priority document, the ‘988 provisional, upon which the Examiner relies to establish disclosure in the prior art, as Yxid, otherwise known as Transposase 30. At the time of filing this provisional application, 9 January 2004, Berka et al. did not disclose, and presumably did not know or appreciate, that the hypothetical ORF of SEQ ID NO:1819 instead encoded RecA protein. It was not until 5 November 2004, the filing date of the application that published as the ‘077 publication, and which is some eight months after the 19 March 2004 priority date claimed by Applicants, that Berka et al. identified SEQ ID NO: 1819 as RecA protein. The United States Court of Appeals for the Federal Circuit has explained that the written description requirement may be satisfied “if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure.” *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003). Berka et al. did not correlate in the prior art the function of RecA protein, since they did not identify it, with the structure they disclosed.

Moreover, the failure of Berka et al. to have correlated the structure of SEQ ID NO: 1819 with its correct function or identification is analogous to the facts analyzed in *In re Fisher*, in which the Federal Circuit, relying heavily on the Supreme Court’s decision in *Brenner v. Manson*, 383 U.S. 519, 86 S.Ct. 1033 (1966), affirmed the decision of the Board of Patent Appeals and Interferences and held that EST sequences lack both specific and substantial utility under 35 USC § 101 and enablement under 35 USC § 112, first paragraph. *In re Fisher*, 421 F.3d 1365, 1379 (Fed. Cir. 2005). The incorrect identification and function of the Berka et al. sequence is equivalent to having made no such identification at all. For these reasons, Applicants respectfully assert that the Berka et al. reference does not provide prior art disclosure of Applicants’ claimed invention.

In view of the above-discussed distinction, the claims of Groups I–IX of Applicants’ application are so linked as to form a single general inventive concept under PCT Rule 13.1 and share the same special technical feature, that of *B. licheniformis* DSM 13 recA protein, required under PCT Rule 13.2. Because the referenced sequences disclosed by Berka et al. lack written

description, utility and enablement, Applicants' claimed invention does makes a contribution over the prior art.

Annex B of the Administrative Instructions under the Patent Cooperation Treaty explains that combinations of claims of different categories particularly are permitted as having unity of invention, including an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process. *See* PCT/AI/8 (e)(iii). Such is application of the claims of Groups I-IX. Applicants' claims fall within this described claim combination, so unity of invention is reached.

In view of the above arguments, Applicants assert that all pending claims within Groups I-IX indeed share the same special technical feature— *B. licheniformis* DSM 13 recA protein. Moreover, Applicants understand that the claims as a whole are directed to a product, a process for making that product and a means for carrying out that process. As the Examiner also will recognize, the arguments made by Applicants in this and the preceding paragraphs reflect the standards that establish unity of invention under 37 CFR §1.475 for, in this case, a national stage application. Accordingly, applicants respectfully request that the Examiner reconsider the restriction requirement and examine all pending claims in one application.

In the event that the Examiner decides to maintain her original restriction requirement, applicants elect Group IV, consisting of claims 17-21 and 23-28 (with traverse). Applicants reserve all rights to pursue the non-elected species in one or more divisional applications, if necessary.

Conclusion

In view of the above amendments and discussion, Applicants believe the pending application is in condition for allowance. Issuance of a Notice of Allowability is requested.

No fees are believed due. However, if any additional fee is due or overpayment is made, please charge or credit our Deposit Account No. 03-2775, under Order No. 13744-00021-US, from which the undersigned is authorized to draw.

Application No. 10/593,425
Amendments, Interview Summary, and Response to
Restriction Requirement and Notice to Comply

Docket No.:H06291 (13744-00021)

Respectfully submitted,

By 

Mark E. Freeman

Registration No.: 48,143
CONNOLLY BOVE LODGE & HUTZ LLP
1007 North Orange Street
P.O. Box 2207
Wilmington, Delaware 19899
(302) 658-9141
(302) 658-5614 (Fax)
Attorney for Applicant

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